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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,214	06/03/1999	KENJI NARAHARA	M2047-3	2546

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/30/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/325,214

Applicant(s)

NARAHARA ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17 & 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed May 6, 2002 has been received. Claims 1-8 are pending.

Claims 1 and 2 have been withdrawn as being directed to a non-elected invention. Election was made without traverse in paper no. 8.

2. This application contains claims drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

3. Claims 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 8 are vague and indefinite because it is unclear what is on the particles that allow them to biologically bind to detectable material. The recitation of a biological bond between the marking elements and the particles is confusing because it is unclear what is on, or in the particles that can allow for a "biological bond". A bond between a biological material, e.g. a specific binding partner, and an inert particle is not a "biological bond".

It is also unclear what characteristics of the marking elements that allows it to bind to the detectable material.

Claims 3 and 8 are also confusing with respect to the wording of the claims; because the specification discloses particles and marking elements comprising antibodies bound to white latex particles and gold sol labeled antibodies, therefore, it is suggested that the claims be amended as follows for clarity:

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Claim 3. (Thrice amended) An A-detection apparatus for detecting the presence of a detectable material in a sample comprising:

a fluid application section for contacting said sample;

a reaction reagent section, ~~[having]~~ containing particles ~~[which are capable of biologically bonding to said detectable material]~~ having antibodies which bind to the detectable material but which do not affect detection of said detectable material when not ~~[biologically bonded]~~ bound to said detectable material, and marking elements movably contained therein, said reaction reagent section connected to said fluid application section such that said sample moves from said fluid application section to said reaction reagent section; wherein said marking element comprises antibodies specific to the detectable material labeled with a detectable marker;

a porous carrier connected to said reaction reagent section such that said sample moves from said reaction reagent section to said porous carrier;

wherein a reaction product is formed from ~~[biological bonding]~~ binding of said detectable material with both said marking elements and said particles when said detectable material is present in said sample; and

a catching section in said porous carrier made from a material having a pore size smaller than a size of said reaction product, such that chromatographic movement of said marking elements not bonded in said reaction product is permitted through said catching section and ~~[whereby]~~ chromatographic movement of said reaction product is restricted~~[whereby]~~ because of the size of said reaction product, thereby causing said reaction product to be retained by said catching section.

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Claim 8. (Thrice amended) A [detection] method for detecting the presence of a detectable material in a sample comprising:

contacting said sample with the apparatus of claim 3; ~~{fluid application section; chromatographically moving said sample through said fluid application section, a reaction reagent section, a porous carrier, and a catching section;~~

~~providing said reaction reagent section}~~

reacting the sample with said particles ~~{which are capable of biologically bonding to said detectable material but which do not affect detection of said detectable material when not biologically bonded to said detectable material}~~ and with said marking elements ~~{reacting said sample with said particles and said marking elements contained in said reaction reagent section to form a reaction product,}~~ such that said detectable material ~~[bonds]~~ binds with both said marking elements and said particles when said detectable material is present in said sample to form a reaction product;

passing said sample, including any reaction product present, through said catching section~~{having a pore size smaller than a size of said reaction product and larger than a particle diameter of said marking elements whereby chromatographic movement of said reaction product is restricted, whereby because of the size of said reaction product, thereby causing said reaction product to be retained by said catching section}~~; and

~~[and]~~ analyzing the presence of said marking elements at said catching section, whereby the presence of said marking elements corresponds with the presence of said detectable material.

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Claims 4-7, "A detection apparatus" should be -The apparatus— for clarity. It is recommended that claims 4-7 be amended as follows:

Claim 4 (amended) ~~[A detection]~~ The apparatus ~~[for detecting the presence of a detectable material in a sample]~~ according to claim 3, wherein said pore size of said catching section is smaller than a ~~[particle]~~ the diameter of said particles.

Claim 5 (amended) ~~[A detection]~~ The apparatus ~~[for detecting the presence of a detectable material in a sample]~~ according to claim 4, wherein said detectable material is selected from at least one of human chorionic gonadotropin, luteinizing hormone, follicle stimulating hormone, thyroid stimulating hormone, insulin, and carcinoembryonic antigen.

Claim 6 (amended) ~~[A detection]~~ The apparatus ~~[for detecting the presence of a detectable material in a sample]~~ according to claim 3, where said pore size of said material of said catching section is larger than ~~[a particle]~~ the diameter of said particles.

Claim 7 (amended) ~~[A detection]~~ The apparatus ~~[for detecting the presence of a detectable material in a sample]~~ according to claim 6, wherein said detectable material is selected from at least one of hepatitis B surface antigen, C-reactive protein, and hemoglobin.

Claim Rejections - 35 USC § 103

4. The rejection of claims 3-8 over Cole et al (US 5,141,850) is withdrawn in view of the amendment to the claims and the argument submitted on May 6, 2002.

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Conclusion

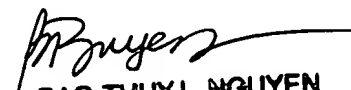
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
July 28, 2003